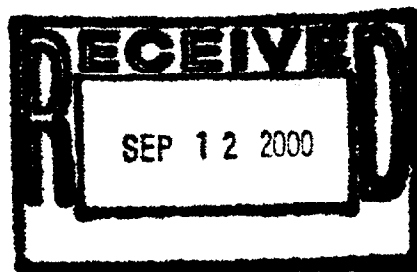




6111 Broken Sound Parkway NW  
Boca Raton, FL 33487-3693  
(561) 241-9400  
Fax (561) 995-5188

September 11, 2000

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown and Rexall brand names bearing the following statement(s) on the label and/or in the labeling:

Calcium XTRA™ with Soy Isoflavones, Vitamin D and Minerals (Sundown): [It] promotes bone strength. The ingredients in Sundown Calcium XTRA work in harmony to help promote the building and maintaining of bone mass and bone density.

Natural Oyster Shell Calcium Plus Vitamin D, Calcium 250 Plus Vitamin D, Calcium 500- Calcium 600, Calcium 600 Plus D, Calcium 900 Plus D, Calcium 1200 Plus D (Sundown): [It] helps the heart and cardiovascular system by maintaining a regular heartbeat and assisting with the transmission of nerve impulses. It helps build and maintain good bone health and is essential for healthy teeth, blood and muscles. [It] may support healthy blood pressure function in some individuals. Vitamin D helps the body absorb calcium.

Calcium Magnesium with Zinc (Sundown): The combination of Calcium, Magnesium and Zinc helps maintain strong bones and healthy teeth. Calcium, a major component of bones and teeth, is also important for proper nerve function, muscle contraction and normal heart rhythm. Magnesium helps regulate calcium flow in cells. It also helps strengthen teeth and aids bone growth. Zinc is necessary for normal metabolism, immune health and cell function.

Calcium 500, Calcium 600 Plus D, Calcium 900, Calcium 1200, Oyster Shell Calcium 1000 (Rexall): [It] helps maintain strong bones and healthy teeth. [It] helps maintain healthy cardiovascular function. [It] supports and promotes healthy, mobile joint function. Regular exercise and a healthy diet that includes adequate amounts of calcium are helpful in building and maintaining bone density. Calcium is vital to many body functions, helping to promote healthy blood, bones, teeth and muscles.

Calcium Magnesium Zinc (Rexall): [It] helps maintain strong bones and healthy teeth. Calcium is a major constituent of bones and teeth and is important for nerve function, muscle contraction and cardiovascular health. Magnesium is one of the prime regulators of calcium flow within cells. Magnesium also helps strengthen teeth and aids bone growth. Zinc is necessary for normal metabolism, immune health and cell function.

975-0162

45885

Also see docket 975-0163

Food and Drug Administration

September 11, 2000

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The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

A handwritten signature in dark ink, appearing to read "Deborah Shur Trinker". The signature is fluid and cursive, with the first name "Deborah" being more prominent.

Deborah Shur Trinker  
Vice President of Regulatory Affairs  
and Assistant General Counsel

Enclosure